Notice of Allowability	Application No.	Applicant(s)	
	09/753,008	SOMLO ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12/8/2005*.

2. ☒ The allowed claim(s) is/are *76-81 and 92-97*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *1/2006* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Reasons for Allowance

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Alan Miller (Reg. No. 42,889) on January 17, 2006.

2. The application has been amended as follows:

In the specification:

Replace "Family 97 - SEQ ID NO:13, Family 1605 - SEQ ID NO:14, Family 1601 - SEQ NO:15" in page 5, line 13 of the specification with --- the human *PKD2* mutation region from Family 97 - SEQ ID NO:13, the human *PKD2* mutation region from Family 1605 - SEQ ID NO:14, and the human *PKD2* mutation region from Family 1601 - SEQ NO:15.

In the claims:

76. (Currently amended) A method of detecting the absence of a mutation in the sequence of polycystic kidney disease type 2 (*PKD2*) gene in a human subject, comprising the steps of:

(a) obtaining a polynucleotide sample containing the sequence of *PKD2* gene from a human subject;

(b) comparing the polynucleotide sample to a reference human wild-type *PKD2* sequence comprising [set forth in] SEQ ID NO:6; and

(c) determining the differences, if any, between the sequence of *PKD2* gene in the polynucleotide sample and the reference wild-type *PKD2* sequence comprising [set forth in] SEQ ID NO:6, wherein an absence of differences between the sequence of *PKD2* gene in the polynucleotide sample and the reference wild-type *PKD2* sequence comprising [set forth in] SEQ ID NO:6 is indicative of the absence of a mutation in the sequence of *PKD2* gene in a human subject.

79. (Currently amended) A method of detecting the absence of a mutation in the sequence of polycystic kidney disease type 2 (*PKD2*) gene (SEQ ID NO:6) in a human subject, comprising the steps of:

(a) obtaining a polynucleotide sample containing the sequence of *PKD2* gene from a human subject, wherein SEQ ID NO:6 is human wild-type *PKD2* gene sequence; and

(b) performing sequence analysis of the polynucleotide sample to detect the absence of a mutation in the sequence of *PKD2* gene (SEQ ID NO:6) of the human subject, wherein the mutation comprises a deletion, insertion, point, or rearrangement mutation.

92. (Currently amended) A method of detecting the presence or absence of a mutation in the nucleotide sequence of polycystic kidney disease type 2 (*PKD2*) gene [set forth in SEQ ID NO:6] in a human subject comprising the steps of:

(a) obtaining a polynucleotide sample containing the sequence of polycystic kidney disease type 2 (*PKD2*) gene from a human subject;

(b) comparing the polynucleotide sample to a [the] nucleotide sequence comprising [set forth in] SEQ ID NO:6, wherein SEQ ID NO:6 is [set forth the] human wild-type *PKD2* gene sequence; and

(c) determining the differences, if any, between the sequence of *PKD2* gene in the polynucleotide sample and the nucleotide sequence comprising [set forth in] SEQ ID NO:6, wherein the human wild-type *PKD2* sequence is [set forth in] SEQ ID NO:6, and thereby detecting the presence or absence of a mutation in the nucleotide sequence of *PKD2* gene [set forth in SEQ ID NO:6] in a human subject.

95. (Currently amended) A method of detecting the presence or absence of a mutation in the sequence of polycystic kidney disease type 2 (*PKD2*) gene in a human subject, comprising the steps of:

(a) obtaining a polynucleotide sample containing the sequence of *PKD2* gene from between genetic markers AFMa059xc9 and AICA1 on chromosome 4 from a human subject, wherein genetic markers AFMa059xc9 and AICA1 flank the *PKD2* gene;

(b) comparing the polynucleotide sample to a reference human wild-type *PKD2* sequence comprising [set forth in] SEQ ID NO:6; and

(c) determining the differences, if any, between the sequence of *PKD2* gene in the polynucleotide sample and the reference wild-type *PKD2* sequence comprising [set forth in] SEQ ID NO:6, wherein the differences are mutations of *PKD2* gene which comprise one or more deletion, insertion, point, or rearrangement mutations; and thereby detecting the presence or absence of a mutation in the sequence of *PKD2* gene in a human subject.

3. The following is an examiner's statement of reasons for allowance:

Claims 76-81 and 92-97 are allowable in light of applicant's amendments filed on December 8, 2005, terminal disclaimer filed on July 7, 2004, and the examiner's amendments. There is no prior art for SEQ ID NO: 6 which is a full-length cDNA of human *PKD2*. The prior art in the record does not teach or reasonably suggest a method of detecting the absence of a mutation in the sequence of polycystic kidney disease type (*PKD2*) gene in a human subject and a method of detecting the presence or absence of a mutation in the nucleotide sequence of polycystic kidney disease type 2 (*PKD2*) gene in a human subject which comprise all of the limitations recited in claims 77, 79, 92, and 95.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Frank Lu
Primary Examiner
January 17, 2005